Exhibit "E"

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE: CELEBREX MARKETING SALES PRACTICES AND PRODUCT LIABILITY LITIGATION

THIS PLEADING RELATES TO:

Aurora Balloveras v. Pfizer, Inc., Case No.: 05-20429-CIV-JORDAN/BROWN (S.D. Fla.)

Dorothy Greaves v. Pfizer, Inc., et al., Case No.: 05-cv-647 (D. Ariz.)

Frankenmuth Fin. Group, et al. v. Pfizer, Inc., et al., Case No.: 05-71656 (E.D. Mich.)

Health Care for All, et al. v. Pfizer, Inc., et al., Case No.: 05-10707 RCL (D. Mass.)

June Swan, et al. v. Pfizer, Inc., et al., Case No.: 05-00834EDL (N.D. Cal.)

North Carolina Fair Share, et al. v. Pfizer, Inc., et al., Case No.: C05-03976-MMC (N.D. Cal.)

Sheet Metal Workers Local No. 20 Welfare & Benefit Fund, et al. v. Pfizer, Inc., et al., Case No.: 1:05-cv-1109-JDT-TAB (S.D. Ind.)

Sheet Metal Workers' Int'l Ass'n Local No. 28 of Metro. New York & Long Island, Case No.: 05 cv 4125 (S.D.N.Y.)

Betty A. Alexander, et al. v. Pfizer, Inc., et al., Case No.: 05-cv-01720-ML-ALC

National Health Ins. Co. v. Pfizer, Inc., et al., Case No.: 05-cv-04073 (N.D. Cal.)

Case No. M:05-CV-01699-CRB

MDL No. 1699

PURCHASE CLAIMS MASTER CELEBREX COMPLAINT

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I. NATURE OF THIS ACTION

A. Procedural Introduction

1. This Master Complaint is submitted to serve the administrative functions of efficiency and economy and to present certain common claims and common questions of fact and law for appropriate action by this Court in the context of this Multidistrict proceeding. This Master Complaint does not include all claims asserted in all of the purchase claims actions that have been transferred to this Court under 28 U.S.C. § 1407. Those matters are set forth in the individual and class actions filed by purchase claims Plaintiffs and served against Defendants. This Master Complaint does not constitute a waiver or dismissal of said actions or the claims asserted therein.

2. This Class Action is brought by and on behalf of all Consumers and Third-Party Payors (Consumers and Third-Party Payors are referred to herein collectively as "Plaintiffs," "Class Members," and "End-Payors") who purchased or paid for the prescription drug Celebrex ("Celebrex"), an anti-inflammatory drug researched, manufactured, marketed, promoted, advertised, sold, and distributed by Defendants Pfizer, Inc. ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle & Co. ("Searle").

3. Pursuant to Rule 23(b)(1), 23(b)(2), 23(b)(3), and/or 23(c)(4)(A) of the Federal Rules of Civil Procedure, Plaintiffs will seek certification of a national End-Payor purchase claims class, through one or more actions transferred to or filed in this Court in the MDL 1699 litigation, consisting of:

> All End-Payors located in the United States, including Consumers and Third-Party Payors,[1] who purchased and/or paid for Celebrex not for resale during the period from December 1, 1998 through the present.[2]

4. Alternatively, in the event that this Court determines that a national End-Payor purchase claims class would not satisfy the requirements for class certification pursuant to Fed. R. Civ. P. 23, Plaintiffs would move for the certification of individual state class actions, grouped

[1] Third-Party Payors include all entities that: (a) provide, sponsor or insure a healthcare plan, which includes prescription drug coverage to natural persons, and (b) purchase, pay or insure all or part of the cost of prescription drugs prescribed and dispensed to those persons pursuant to a health plan.

[2] For further refinement of the class definition *see* Section VI, *infra*.

according to commonalities of state law consisting of, as to each state for which certification is sought:

> All End-Payors located in [State], including consumers and Third-Party Payors, who purchased and/or paid for Celebrex not for resale during the period from December 1, 1998 through the present.

5. In the event that Plaintiffs are directed to pursue the statewide class course of action set forth in the forgoing paragraph, Plaintiffs intend to request the Panel for Multi-District Litigation ("MDL Panel" or "Panel") to remand, to its transferor forum, each state class action as to which Plaintiffs seek certification, solely for purposes of addressing the class certification question. Remand of the class certification question will allow appellate review of the statewide class certification question by the appropriate Circuit Court(s), thus ensuring that no party will have been prejudiced by the Panel's random selection of a transferee forum whose procedural jurisprudence would determine the class certification issue differently from that of the transferor forum that is charged with its ultimate trial. For purposes of uniformity and judicial efficiency, Plaintiffs would further move the MDL Panel to appoint this Court to sit, by *ad hoc* designation, over the class certification issue in each transferor court as to which such remand is sought.

B. Summary of Allegations

6. Non-steroidal anti-inflammatory drugs ("NSAIDs") have been widely used to treat arthritis, acute and chronic pain for nearly 40 years. Although they relieve symptoms in certain patients, such relief comes at the expense of important adverse effects, most notably upper gastrointestinal toxicity. Use of NSAIDs leads to admission to hospital for ulcer complications (bleeding and perforation) in around 1% of users annually and results in thousands of deaths every year.

7. The emergence of NSAIDs that selectively inhibit the cyclo-oxygenase 2 ("COX-2") isoform, which is inducible and expressed at sites of inflammation, while sparing COX-1, associated with gastroprotection, was an apparent pharmacological breakthrough promising real hope of a better future for NSAIDs.

8. Celebrex was one of the new COX-2 inhibitors, Vioxx was the other. Defendants believed that Celebrex had the potential to be a new blockbuster drug with yearly sales in the billions of dollars. As part of the unlawful scheme set forth below, Defendants embarked on a massive marketing campaign directed to both doctors and consumers to accomplish that objective. Television, print and other promotional materials gave the impression that Celebrex was a "breakthrough" drug clinically superior to older and far less expensive NSAIDs.

9. Defendants represented that Celebrex provided symptomatic relief similar to ibuprofen and naproxen but was clinically superior because it was significantly less likely to cause the gastrointestinal adverse side effects commonly associated with other non-steroidal anti-inflammatory drugs. For instance, NSAIDs can, in a limited group of patients, cause gastrointestinal perforations, ulcers and bleeding with long-term use. Pfizer promoted Celebrex as a safe and effective alternative that would have less deleterious and painful impact on the gut, but that would be just as effective, if not more so, for pain relief.

10. The extent to which a drug is paid for by Third-Party Payors is determined by that drug's status on the Third-Party Payor's "formulary," which is a list of drugs that plan participants are authorized to purchase for payment under the benefit plan.

11. Placement of a prescription drug on the formularies of Third-Party Payors, medical care organizations, and or prescription benefit managers (who are employed by the Third-Party Payors to design or administer the benefit plans) is critical to the success of the drug. Defendants knew that preferred placement on these formularies would guarantee commercial success for Celebrex.

12. In an elaborate and sophisticated manner, Defendants aggressively marketed Celebrex directly to consumers and medical professionals (including physicians and leading medical scholars) in order to leverage pressure on Third-Party Payors, medical care organizations, and large institutional buyers (*e.g.*, hospitals) to include Celebrex on their formularies. Faced with the increased demand for the drug by consumers and health care professionals that resulted from Celebrex's successful advertising and marketing blitz, Third-Party Payors were compelled to add

Celebrex to their formularies. Celebrex's marketing campaign specifically targeted Third-Party Payors, physicians, and consumers, and was designed to convince them of both the therapeutic and economic value of Celebrex.

13. Defendants' marketing and promotion of Celebrex was part of a scheme to create the impression and demand for Celebrex as a wide-ranging pain reliever that would enhance consumers' abilities to live a normal life or engage in activities such as running, playing a guitar, swimming, walking, taking exercise classes and a host of similar activities that many who suffer from chronic pain have difficulty performing. The scheme was accomplished by unlawful means including, but not limited to: (i) the suppression of data showing the cardiovascular risks associated with the use of Celebrex; (ii) the manipulation of data in an effort to show that Celebrex "when used for 6 months…is associated with a lower incidence of combined clinical upper GI events than comparator NSAIDs (ibuprofen and diclofenac) used at standard therapeutic dosages." [JAMA.2000;284:1247-1255] when in fact: (a) the prespecified endpoint of the CLASS trial had been specifically defined as "Clinically Significant Upper Gastrointestinal Events" not the combination of symptomatic and serio us complications reported as the endpoint in the JAMA report of the CLASS study[3]; (b) the study lasted 12 not six months; (c) even during the first six months of the study reported in JAMA patients taking Celebrex did not develop significantly fewer serious GI complications than those taking older NSAIDs; and (d) in fact, use of Celebrex for more than six months ***increased*** the risk of GI complications; (iii) the manipulation of data to give the appearance of superiority over NSAIDs in pain efficacy and safety when such superiority did not exist; (iv) false promotional materials directed to doctors and consumers; and (v) the use of reprinted articles from prestigious medical journals that falsely claimed Celebrex was proven to be safer than NSAIDs.

[3] "The definition of CSUGIEs [is that] chosen by the sponsor is …. This is a clinically meaningful definition and represents a major advance in the study of UGI toxicity of NSAIDs." From Medical Officer's Gastroenterology Advisory Committee Briefing Document, Lawrence Goldkind MD, **http://www.fda.gov/ohrms/dockets/ac/01/briefing/3677b1_05_gi.doc**

14. From 1999 through 2003, Defendants spent approximately $400 million on direct-to-consumer advertising for Celebrex. This expensive marketing effort paid off. In 2004, Celebrex achieved $3.3 billion in worldwide sales, 82% of which occurred in the United States[4/5] (the US and New Zealand – with a population of less than 4 million -- are the only two industrialized countries that allow direct-to-consumer advertising). In 2004, Celebrex accounted for 6.3% of Pfizer's total worldwide sales of $52.5 billion.

15. As a result of Defendants' scheme, they were able to create a market for Celebrex and to sell Celebrex at a premium price over NSAIDs and to have it become a standard treatment option as opposed to use of less expensive NSAIDs. Also part of Defendants' scheme was their role in the American College of Rheumatology's guidelines for the treatment of osteoarthritis of the hip and knee issued in September, 2000. These guidelines called for the use of Celebrex or Vioxx if acetaminophen failed to provide adequate relief. Three out of the four authors had financial ties to the Defendants at the time these guidelines were written.

16. The success of Defendants' scheme was recently documented in a study released on January 24, 2005, in the ARCHIVES OF INTERNAL MEDICINE, Volume 165, entitled *National Trends in Cyclooxygenage-2 Inhibitor Use Since Market Release*. The authors of that study concluded that the "aggressive marketing techniques to patients and physicians" caused a growth not only in use of COX-2 inhibitors but also in overall market demand.

17. In fact, Celebrex has been promoted as a superior pain reliever when for most patients it has no proven superiority over other NSAIDs. Celebrex sells for $2.53 to $6.45 per day depending upon the dose, while NSAIDs sell for $0.21 to $0.31 per day. Billions of dollars have thus been wasted in which Plaintiffs and Class Members have paid a premium price for a drug that is not a premium or superior product over equally available NSAIDs and other paid medications. If Defendants had not engaged in the wrongful marketing, advertising and promotion of Celebrex, Plaintiffs and Class Members would have paid for other equally effective and less expensive

[4] $2.7 billion in US sales in 2004: http://money.cnn.com/2006/01/17/news/companies/pfizer/

[5] $3.3 billion in worldwide sales in 2004: http://money.cnn.com/2006/01/17/news/companies/pfizer/

medications. Had the truth been told about its safety and efficacy, Celebrex would have sold at a price similar to that of other NSAIDs and would not have become a standard in the treatment of arthritis and other forms of pain relief. The study in the ARCHIVES OF INTERNAL MEDICINE found that 63% of patients who received COX-2 inhibitors were at a low risk for developing the ulcers and gastrointestinal problems that the COX-2 inhibitors were aimed at preventing, and that Defendants' marketing scheme had played a significant role in over use of COX-2 inhibitors for this type of patient. In fact, the ARCHIVES study understates the lack of a need for Celebrex. A Federal Drug Administration ("FDA") reviewer found that Celebrex "did not appear to offer a unique advantage to high-risk patients." Thus in both the non-risk and at-risk population, Celebrex was neither more effective nor safer than other NSAIDs.

18. In this action Plaintiffs seek damages arising from the purchases of Celebrex resulting from Defendants' illegal scheme and/or conduct.

II. JURISDICTION

19. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. § 1331 because this action arises under the laws of the United States, 18 U.S.C. § 1964(c), and because this action alleges violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §§ 1961-1968. This Court also has subject-matter jurisdiction under 15 U.S.C. § 1.

20. This Court also has diversity subject-matter jurisdiction over this class action pursuant to the Class Action Fairness Act of 2005, which, *inter alia*, amends 28 U.S.C. § 1332 to add a new subsection (d) conferring federal jurisdiction over class actions where, as here, "any member of a class of plaintiffs is a citizen of a State different from any defendant" and the aggregated amount in controversy exceeds five million dollars ($5,000,000). *See* 28 U.S.C. §§ 1332(d)(2) and (6). This Court has personal jurisdiction over the parties because Plaintiffs submit to the jurisdiction of the Court and Defendants systematically and continually conduct business throughout the State of California, including marketing, advertising, and sales directed to California residents.

III. PARTIES

A. Plaintiffs

21. Plaintiff Aurora Balloveras ("Balloveras"), who filed Civil Action No. 05-20429-CIV-JORDAN/BROWN (S.D. Fla.), is a resident of Miami-Dade County, Florida, and is otherwise *sui juris*. During the proposed Class Period, Balloveras was prescribed, purchased and consumed Celebrex within the state of Florida based on the cumulative impact of Defendants' wrongful conduct as alleged herein and was damaged as a direct and foreseeable result of such conduct.

22. Plaintiff Bricklayers of Indiana Welfare Fund ("Bricklayers"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 9045 East 59th Street, Indianapolis, Indiana 46219. Bricklayers is an "employee welfare benefit plan" and an "employee benefit plan" as defined in the Employee Retirement Income Security Act ("ERISA"). Bricklayers is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

23. Plaintiff California Public Interest Research Group, Inc. ("CALPIRG"), who filed Civil Action No. 05-00834EDL (N.D. Cal.), is one of California's leading public interest advocacy groups and has approximately 20,000 members. It is located at 1107 9th Street, Suite 601, Sacramento, California. During the Class Period, CALPIRG members purchased Celebrex and were injured by the illegal conduct alleged herein. Such members include Robert Dawson, Laura S. Rasmussen, and Rosalind Hamilton. Mr. Dawson took Celebrex for approximately four years to treat lower back and sciatic nerve pain, and he paid co-payments through his insurance plan. Ms. Rasmussen took Celebrex for the treatment of osteoarthritis, and she paid co-payments through her insurance plan. Ms. Hamilton took Celebrex for at least three years to treat arthritis, and paid co-payments through her insurance plan. As an unincorporated association whose

members have suffered injury in fact and have lost money or property as a result of the illegal conduct alleged herein, CALPIRG has standing to pursue this class action on behalf of itself and all those similarly situated based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

24. Plaintiff Cavalier Homes, Inc. ("Cavalier"), who filed Civil Action No. 05-10707 (D. Mass.), is a Delaware corporation with its principal place of business in Alabama. Cavalier purchased drugs, including Celebrex, on behalf of its employees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

25. Plaintiff Commonwealth Care Alliance ("CCA"), who filed Civil Action No. C05-03976-MMC (N.D. Cal.), is a prepaid care system contracting with Medicare and Massachusetts Medicaid to provide comprehensive care to vulnerable, high-cost populations. It is located in Boston, Massachusetts. CCA is a Third-Party Payor that paid for Celebrex on behalf of its beneficiaries during the relevant time period, and was injured by the illegal conduct described in this Complaint. CCA has standing to bring this action on behalf of itself and all other Third-Party Payors who paid for Celebrex based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

26. Plaintiff Frankenmuth Financial Group, Inc. ("Frankenmuth"), who filed Civil Action No. 05-71656 (E.D. Mich.), is an entity maintaining its principal place of business at Frankenmuth, Michigan. Frankenmuth (or its members) has paid for purchases of Celebrex based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

27. Plaintiff Dorothy Greaves ("Greaves"), who filed Civil Action No. 05-cv-647 (D. Ariz.), is a resident of Arizona. She purchased Celebrex in Arizona. Had she known the truth about Celebrex, she would not have purchased it and/or certainly not at the price she paid when it was substantially inflated. Greaves pursues this class action on behalf of herself and all others

similarly situated based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

28. Plaintiff Sarah Hare ("Hare"), who filed Civil Action No. 05-00834EDL (N.D. Cal.), is an individual residing in California. Plaintiff Hare purchased Celebrex and was injured by the illegal conduct alleged herein. Specifically, she has taken Celebrex for approximately four years in the treatment of lower back and hip pain. She pays co-payments through her insurance plan. As an individual, Plaintiff Hare pursues this class action on behalf of herself and all those similarly situated based on the cumulative impact of Defendants' wrongful conduct as alleged herein and was damaged as a direct and foreseeable result of such conduct.

29. Plaintiff Beatrice Howard ("Howard"), who filed Civil Action No. 05-00834EDL (N.D. Cal.), is an individual residing in California. Plaintiff Howard purchased Celebrex and was injured by the illegal conduct alleged herein. Specifically, she took Celebrex for approximately three years to treat arthritis. She paid co-payments through her insurance plan. As an individual, Plaintiff Howard pursues this class action on behalf of herself and all those similarly situated based on the cumulative impact of Defendants' wrongful conduct as alleged herein and was damaged as a direct and foreseeable result of such conduct.

30. Plaintiff Health Care For All ("HCFA"), who filed Civil Action No. 05-10707 RCL (D. Mass.), is a consumer health advocacy organization that has led the fight in Massachusetts to expand access to affordable, quality health care since 1985. It is located in Boston, Massachusetts. HCFA's members purchase and have purchased Celebrex during the relevant Period and were injured by the illegal conduct described in this Complaint. As an organizational Plaintiff, HCFA has standing to bring this action on behalf of itself and all consumers in the Commonwealth of Massachusetts based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

31. Plaintiff IBEW 673 Fringe Benefit Funds Fund ("IBEW 673"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 8358 Munson Road, Mentor, Ohio 44060. IBEW 673 is an "employee welfare benefit

plan" and an "employee benefit plan" as defined in the Employee Retirement Income Security Act ("ERISA"). IBEW 673 is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

32. Plaintiff IBEW Local 32 Health and Welfare Fund ("IBEW 32"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 1975 North West Street, Lima, Ohio 45801. IBEW 32 is an "employee welfare benefit plan" and an "employee benefit plan" as defined in the Employee Retirement Income Security Act ("ERISA"). IBEW 32 is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

33. Plaintiff IBEW Local 129 Fringe Benefit Funds ("IBEW 129"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 36964 Detroit Road, Avon, Ohio 44011. IBEW 129 is an "employee welfare benefit plan" and an "employee benefit plan" as defined in the Employee Retirement Income Security Act ("ERISA"). IBEW 129 is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

34. Plaintiff IBEW Local 683 Fringe Benefit Funds ("IBEW 683"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 23 West Second Avenue, Columbus, Ohio 43201. IBEW 683 is an "employee welfare benefit plan" and an "employee benefit plan" as defined in the Employee Retirement Income Security Act ("ERISA"). IBEW 683 is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

35. Plaintiff Indiana Carpenters Health and Welfare Fund ("ICHWF"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 2635 Madison Avenue, Indianapolis, Indiana 46225. ICHWF is an "employee welfare benefit plan" and an "employee benefit plan" as defined in the Employee Retirement Income Security Act ("ERISA"). ICHWF is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

36. Plaintiff Indiana Electrical Workers Benefit Trust ("IEWBT"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 1828 N. Meridian Street, Suite 103, Indianapolis, Indiana 46202. IEWBT is an "employee welfare benefit plan" and an "employee benefit plan" as defined in the Employee Retirement Income Security Act ("ERISA"). IEWBT is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive

healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

37. Plaintiff Indiana State Council of Carpenters Health and Welfare Fund ("ISC"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 5420 West Southern Avenue, Suite 407, Indianapolis, Indiana 46241. ISC is an "employee welfare benefit plan" and an "employee benefit plan" as defined in the Employee Retirement Income Security Act ("ERISA"). ISC is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

38. Plaintiff Indiana State District Council of Laborers and Hod Carriers Welfare Fund ("ISDC"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 413 Swan Street, Terre Haute, Indiana 47807. ISDC is an "employee welfare benefit plan" and an "employee benefit plan" as defined in the Employee Retirement Income Security Act ("ERISA"). ISDC is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

39. Plaintiff Indiana State Council of Roofers Health and Welfare Fund ("Roofers"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its

principal place of business at 1345 Northside Boulevard, South Bend, Indiana 46615. Roofers is an "employee welfare benefit plan" and an "employee benefit plan" as defined in the Employee Retirement Income Security Act ("ERISA"). Roofers is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

40. Plaintiff Georgia Katsanos ("Katsanos"), who filed Civil Action No. 05-00834EDL (N.D. Cal.), is an individual residing in California. Plaintiff Katsanos purchased Celebrex and was injured by the illegal conduct alleged herein. Specifically, she has taken Celebrex for at least four years. She paid co-payments through her insurance plan. As an individual, Plaintiff Katsanos pursues this class action on behalf of herself and all those similarly situated based on the cumulative impact of Defendants' wrongful conduct as alleged herein and was damaged as a direct and foreseeable result of such conduct.

41. Plaintiff National Healthcare Insurance Company, who filed Civil Action C05-04073 (N.D. Cal.) is a life and health insurance company with its principal place of business at 1901 North State Highway 360, Grand Prairie, Texas 75050, and is involved in the business of providing health benefits, among others, to covered lives. Plaintiff paid for prescriptions Celebrex dispensed to covered lives in several states. Plaintiff has paid and provided, and will in the future pay and provide, health care benefits to its members and insureds as a direct result of the wrongful conduct of Defendant as fully alleged herein.

42. Plaintiff Rose Lohman ("Lohman"), who filed Civil Action No. 05-05-10707 RCL (D. Mass.), has been taking Celebrex for ten years, has paid for Celebrex and has been injured as a result based on the cumulative impact of Defendants' wrongful conduct as alleged herein and was damaged as a direct and foreseeable result of such conduct.

43. Plaintiff Michelle Madoff ("Madoff"), who filed Civil Action No. 05-10707 RCL (D. Mass.), is a resident of the State of Arizona. Until recently Madoff took Celebrex and has made out-of-pocket payments for Celebrex based on the cumulative impact of Defendants' wrongful conduct as alleged herein and was damaged as a direct and foreseeable result of such conduct.

44. Plaintiff Helen Marconi ("Marconi"), who filed Civil Action No. C05-03976-MMC (N.D. Cal.), is a resident of Bronx, New York. During the relevant time period, she purchased Celebrex and was injured by the illegal conduct described in this Complaint based on the cumulative impact of Defendants' wrongful conduct as alleged herein and was damaged as a direct and foreseeable result of such conduct.

45. Plaintiff Robert Mariconi ("Mariconi"), who filed Civil Action No. C05-03976-MMC (N.D. Cal.), is a resident of Saddle Brook, New Jersey. During the relevant time period, he purchased Celebrex and was injured by the illegal conduct described in this Complaint based on the cumulative impact of Defendants' wrongful conduct as alleged herein and was damaged as a direct and foreseeable result of such conduct.

46. Plaintiff Evelyne Mayes ("Mayers"), who filed Civil Action No. C05-03976-MMC (N.D. Cal.), is a resident of Indianapolis, Indiana. During the relevant time period, she purchased Celebrex and was injured by the illegal conduct described in this Complaint based on the cumulative impact of Defendants' wrongful conduct as alleged herein and was damaged as a direct and foreseeable result of such conduct.

47. Plaintiff Judith C. Meredith ("Meredith"), who filed Civil Action No. 05-10707 (D. Mass.), is a resident of the Commonwealth of Massachusetts residing in Dorchester, Massachusetts. During the relevant period, Meredith purchased Celebrex and was injured by the illegal conduct described in this Complaint. Specifically, she began taking Celebrex approximately two years ago to treat pre-arthritis pains. She had previously taken ibuprofen. She began taking Celebrex after seeing the advertisements and asked her doctor to prescribe it for her. She has paid co-payment amounts to purchase Celebrex through her prescription drug coverage plan provided

through her husband's employer. As an individual, Meredith pursues this class action on behalf of herself and those similarly situated based on the cumulative impact of Defendants' wrongful conduct as alleged herein and was damaged as a direct and foreseeable result of such conduct.

48. Plaintiff Michiana Area Electrical Workers Health and Welfare Fund ("Michiana"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 1345 Northside Boulevard, South Bend, Indiana 46615. Michiana is an "employee welfare benefit plan" and an "employee benefit plan" as defined in the Employee Retirement Income Security ct (ERISA"). Michiana is a non-profit trust, sponsored and administered by the Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

49. Plaintiff Mary Morris ("Morris"), who filed Civil Action No. C05-03976-MMC (N.D. Cal.), is a resident of Fort Wayne, Indiana. During the relevant time period, she purchased Celebrex and was injured by the illegal conduct described in this Complaint based on the cumulative impact of Defendants' wrongful conduct as alleged herein and was damaged as a direct and foreseeable result of such conduct.

50. Plaintiff New England Carpenters Health Benefits Fund ("Carpenters"), who filed Civil Action No. C05-03976-MMC (N.D. Cal.), is an employee welfare benefit plan established and maintained pursuant to sections 1002(1) and (3) of ERISA, for the purposes of providing health benefits to eligible participants and beneficiaries. As such, Carpenters is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. § 1132(d). Carpenters maintains its principal place of business in Wilmington, Massachusetts. It provides comprehensive health coverage for over 22,000 participants and beneficiaries in the states of Maine, New Hampshire, Vermont and Massachusetts. Carpenters is a Third-Party Payor that paid for Celebrex on behalf of

its beneficiaries during the relevant time period, and was injured by the illegal conduct described in this Complaint. Carpenters has standing to bring this action on behalf of itself and all other Third-Party Payors who paid for Celebrex based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

51. Plaintiff North Carolina Fair Share ("NCFS"), who filed Civil Action No. C05-03976-MMC (N.D. Cal.), is a consumer health advocacy organization that has led the fight in North Carolina to expand access to affordable, quality health care. It is located in Raleigh, North Carolina. NCFS's members purchase and have purchased Celebrex during the relevant time period and were injured by the illegal conduct described in this Complaint. As an organizational Plaintiff, NCFS has standing to bring this action on behalf of itself and all consumers in North Carolina based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

52. Plaintiff Ohio State IBEW Health and Welfare Fund ("Ohio State"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 947 Goodale Boulevard, Columbus, Ohio 43216. Ohio State is an "employee welfare benefit plan" and an "employee benefit plan" as defined in the Employee Retirement Income Security Act ("ERISA"). Ohio State is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

53. Plaintiff Painters Local No. 469 Health and Welfare Fund ("Painters 469"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 7730 North 500 East, Decatur, Indiana 46615. Painters 469 is an "employee welfare benefit plan" and an "employee benefit plan" as defined in the Employee Retirement Income Security Act ("ERISA"). Painters 469 is a non-profit trust, sponsored and administered by

a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

54. Plaintiff Painting Industry Insurance and Annuity Funds ("PIIAF"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 8257 Dow Circle, Cleveland, Ohio 44136. PIIAF is an "employee welfare benefit plan" and an "employee benefit plan" as defined in the Employee Retirement Income Security Act ("ERISA"). PIIAF is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

55. Plaintiff Pipe Trades Industry Health and Welfare Plan ("Pipe Trades"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 8838 East Milner, Terre Haute, Indiana 47803. Pipe Trades is an "employee welfare benefit plan" and an "employee benefit plan" as defined in the Employee Retirement Income Security Act ("ERISA"). Pipe Trades is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

56. Plaintiff Plumbers and Steamfitters Local 42 Health & Welfare Plan ("Plumbers 42"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity,

maintaining its principal place of business at 187 Woodlawn Avenue, Norwalk, Ohio 44857. Plumbers 42 is an "employee welfare benefit plan" and an "employee benefit plan" as defined in the Employee Retirement Income Security Act ("ERISA"). Plumbers 42 is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

57. Plaintiff Plumbers and Steamfitters Local No. 166 Health and Welfare Plan ("Plumbers 166"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 2930 West Ludwig Road, Fort Wayne, Indiana 46818. Plumbers 166 is an "employee welfare benefit plan" and an "employee benefit plan" as defined in the Employee Retirement Income Security Act ("ERISA"). Plumbers 166 is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

58. Plaintiff Plumbers Local No. 210 Health and Welfare Fund ("Plumbers 210"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 2901 East 83rd Place, Merrillville, Indiana 46410. Plumbers 210 is an "employee welfare benefit plan" and an "employee benefit plan" as defined in the Employee Retirement Income Security Act ("ERISA"). Plumbers 210 is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive

healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

59. Plaintiff Service Employee International Union Local No. 3 Health & Welfare Fund ("Service Employee") who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 1735 East 23rd, Cleveland, Ohio 44114. Service Employee is an "employee welfare benefit plan" and an "employee benefit plan" as defined in the Employee Retirement Income Security Act ("ERISA"). Service Employee is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

60. Plaintiff Sheet Metal Workers Local No. 20 Welfare and Benefit Fund ("Sheet Metal 20"), who filed Civil Action No. 1:05-cv-1109-JDT-TAB (S.D. Ind.), is an entity maintaining its principal place of business at 2828 East 45th Street, Indianapolis, Indiana 46220. Sheet Metal 20 is an "employee welfare benefit plan" and an "employee benefit plan" as defined in the Employee Retirement Income Security Act ("ERISA"). Sheet Metal 20 is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

61. Plaintiff Sheet Metal Workers' International Association Local No. 28 of Metropolitan New York & Long Island ("Sheet Metal 28"), who filed Civil Action No. 05 cv 4125 (S.D.N.Y.), is a labor union health and welfare fund that provides health and prescription drug benefits to its member in Metropolitan New York and Long Island, and specifically, it has paid or reimbursed members for prescription drug benefits including for the purchase of the drug Celebrex. Sheet Metal 28 is headquartered in Mineola, New York. Sheet Metal 28 (or its members) purchased Celebrex based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

62. Plaintiff Southern Ohio Painters Health and Welfare Fund ("S. Ohio"), who filed Civil Action No. 1:05 01-cv 1109 JDT-TAB (S.D. Ind.), is an entity, maintaining its principal place of business at 2621 East Third Street, Dayton, Ohio 45403. S. Ohio is an "employee welfare benefit plan" as defined in the Employee Retirement Income Security Act ("ERISA"). S. Ohio is a non-profit trust, sponsored and administered by a Board of Trustees, established through collective bargaining by labor unions and employers. Pursuant to the trust agreement under which it was created, it provides comprehensive healthcare benefits to participants who are employed under various collective bargaining agreements, along with their dependents and retirees based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

63. Plaintiff Steamfitters' Industry Welfare Fund ("Steamfitters"), who filed Civil Action No. 05 cv 3814 (S.D.N.Y.), is a union health and welfare fund that provides health and prescription drug benefits to its members, and specifically, it has paid or reimbursed members for prescription drug benefits for Bextra for its members and was injured by the illegal conduct alleged herein. Steamfitters is headquartered in the city of New York, in the State of New York.

64. Plaintiff June Swan ("Swan"), who filed Civil Action No. 05-00834EDL (N.D. Cal.), is an individual residing in California. Plaintiff Swan purchased Celebrex and was injured by the illegal conduct alleged herein. Specifically, she has taken Celebrex for approximately two years in the treatment of arthritis and hip pain. She pays co-payments through her insurance plan.

As an individual, Plaintiff Swan pursues this class action on behalf of herself and all those similarly situated based on the cumulative impact of Defendants' wrongful conduct as alleged herein and was damaged as a direct and foreseeable result of such conduct.

65. Plaintiff United Senior Action of Indiana ("USAI"), who filed Civil Action No. 05-10707 RCL (D. Mass.), is a consumer health advocacy organization that had fought to expand access to affordable, quality health care. It is located in Indiana. Its members have purchased Celebrex during the relevant period and were injured by the illegal conduct described in this Complaint. As an organizational Plaintiff, USAI has standing to bring this action on behalf of itself and all consumers in Indiana based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

66. Plaintiff Linda A. Watters, Commissioner ("Wattters"), who filed Civil Action No. 05-71656 (E.D. Mich.), Offices of Financial and Insurance Services for the State of Michigan in her capacity as Rehabilitator of The Wellness Plan and in her capacity as Liquidator of Michigan Health Maintenance Organization Plans, Inc., formerly known as OmniCare Health Plan, Inc., is a Michigan official whose function is to collect and liquidate all assets and liabilities of the former private Third-Party Payors Wellness Plan and OmniCare. At all times relevant to this Complaint, Wellness Plan and OmniCare were private Third-Party Payors whose function was to assume the risk of payment of medical and prescription costs on behalf of the participants in its plan. Wellness Plan and Omnicare paid for purchases of Celebrex based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

67. Plaintiff Wisconsin Citizen Action ("WCA"), who filed Civil Action No. 05-10707 RCL (D. Mass.), is a consumer health advocacy organization that had fought to expand access to affordable, quality health care. It is located in Wisconsin. Its members have purchased Celebrex during the relevant period and were injured by the illegal conduct described in the Complaint. As an organizational Plaintiff, it has standing to bring this action on behalf of itself and all consumers

in Wisconsin based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

68. Plaintiff Stephen Keisker is a resident of Danville, Hendricks County, Indiana. Mr. Keisker paid for the entire cost of his Celebrex prescription out-of-pocket. He took Celebrex between 1999 and 2001 and was economically injured as described herein.

69. Plaintiff Betty A. Alexander, who filed Civil Action No. 05-1720 (E.D. La.), is a person of the full age of majority domiciled in Orleans Parish, Louisiana, and is a Louisiana consumer who paid for the prescription drug Celebrex.

70. Plaintiff Allied Services Division Welfare Fund ("ASD"), who filed Civil Action No. 05-1720 (E.D. La.), a division of Transportation Communication International Union – AFL-CIO, CLC ("TCU"), is a health and welfare benefit fund with its principal place of business at 53 West Seegers Road, Arlington Heights, Illinois 60005, and is involved in the business of providing health and pension benefits, among others, to covered lives. ASD is a multi-employer employee welfare benefit plan within the meaning of the Employee Retirement Income Security Act, 29 U.S.C. § 1001(2), and § 1002(37). ASD paid for prescriptions of Celebrex dispensed to covered lives in several states. ASD has paid and provided, and will in the future pay and provide, health care benefits to its members and insureds as a direct result of the wrongful conduct of the Defendant as fully alleged herein.

71. Each of the plaintiffs (or its members) purchased Celebrex based on the cumulative impact of Defendants' wrongful conduct as alleged herein and were damaged as a direct and foreseeable result of such conduct.

B. Defendants

72. Defendant Pharmacia is a Delaware corporation with its principal place of business in New Jersey. At all relevant times, Pharmacia has been engaged in the business of marketing and selling Celebrex nationwid.

81. Traditional NSAIDs, like aspirin, reduce pain sensations by inhibiting both COX-1 and COX-2 enzymes simultaneously. As would be expected, traditional NSAIDs increase the risk of ulcers in the stomach and intestines. However, because of a complex chemical balance in the human body, traditional NSAIDs do not cause blood clots, but aspirin reduces the risk of clots and helps to protect heart function.

82. It is generally accepted in the medical community that blocking the COX-2 enzyme encourages the formation of blood clots and increases the risk of various clot-related cardiovascular events, including: heart attack, stroke, unstable angina, cardiac clotting and hypertension.

83. It is generally accepted in the medical community that blocking the COX-2 enzyme encourages the formation of blood clots and causes various clot-related cardiovascular events, including: heart attack, stroke, unstable angina, cardiac clotting and hypertension.

84. Traditional NSAIDs, like aspirin, reduce pain sensations by inhibiting both COX-1 and COX-2 enzymes simultaneously. As would be expected, traditional NSAIDs may cause ulcers in the stomach and intestines. However, because of a complex chemical balance in the human body, traditional NSAIDs do not cause blood clots, but aspirin reduces the risk of clots and helps to protect heart function.

85. For decades, in the absence of other treatment options, consumers seeking pain relief were forced to accept and live with the gastrointestinal risks of traditional NSAIDs.

86. Defendants set out to remedy this problem by developing "selective" inhibitors that would block only COX-2 production, and thus (theoretically) allow the proper maintenance of gastric tissue while still reducing pain and inflammation sensations.

87. The emergence of NSAIDs that selectively inhibit the cyclo-oxygenase 2 (COX-2) isoform, which is inducible and expressed at sites of inflammation, while sparing COX-1, associated with gastroprotection, was a pharmacological breakthrough promising real hope of a better future for NSAIDs.

B. FDA Approval

88. Defendant Searle sought FDA approval for Celebrex on June 29, 1998. In its pre-approval marketing plans, Defendants planned that Celebrex would be approved and that such approval would include an indication that it was safer than NSAIDs in protecting against GI complications. The treatment of arthritis pain with reduced GI complications was the single most important attribute to the planned marketing and promotion of Celebrex and its place as a new blockbuster drug.

89. Pre-approval marketing plans stressed that Celebrex was superior to NSAIDs and thus a "breakthrough" in science and safety. Pre-approval plans were to promote Celebrex as offering a significant reduction in GI complications.

90. The FDA granted new drug approval on December 23, 1999. However, Defendants did not obtain approval to promote Celebrex as less likely to cause clinically serious GI events than conventional NSAIDs. The FDA warned Searle that any promotional activities "that make or imply comparative claims about the frequency of clinically serious GI events compared to NSAIDs or specific NSAIDs will be considered false and/or misleading...." This finding by the FDA was a potentially serious blow to Defendants.

91. As a result, the Celebrex package inserts had to include a warning that serious gastrointestinal toxicity "can occur at any time, with or without warning symptoms, in patients treated with nonsteroidal anti-inflammatory drugs (NSAIDs)."

C. The CLASS Study

92. Defendants funded a significant clinical trial to demonstrate that Celebrex had greater gastrointestinal safety than traditional NSAIDs: the Celecoxib Long-Term Arthritis Safety Study ("CLASS").

93. Defendants expected CLASS to show that Celebrex was statistically significant in reducing serious GI complication over NSAIDs and that the results would allow removal of the warning label. Removal of the warning label was viewed as critical to breaking the NSAID barrier, *i.e.*, competing against NSAIDs based on GI superiority.

101. CLASS, which included over 8,000 people with rheumatoid and osteoarthritis, compared the risk of gastrointestinal problems in people taking Celebrex with the risk in those taking ibuprofen (Motrin, Advil) and diclofenac (Voltaren). ***The article in JAMA concluded that Celebrex, "when used for 6 months ... is associated with a lower incidence of clinical upper GI events than comparator NSAIDs (ibuprofen and diclofenac)."*** The accompanying editorial supported this conclusion: "The results of this important study ... provide ***promising data*** to suggest that [Celebrex is] ... ***effective in reducing***, but not eliminating, the risk of symptomatic [minor] ulcers and [major] ulcer complications in the enormous number of individuals who might benefit from these drugs...."

102. There was, however, one very large problem. The manufacturer's original research plan, as submitted to the FDA, had defined the duration of the CLASS study that compared Celebrex with ibuprofen as 12 months, and that of the study comparing Celebrex with diclofenac as 16 months. And, indeed, the combined study had run for a full 12 months. ***The authors, however, submitted only the first six months of data for the article in JAMA.*** Peer reviewers, editors, and editorialists had no way of knowing that the study had last for 12, not six, months. As a result, data from the ***second*** six months of the study were unreported and invisible to even the most careful readers of the JAMA article. The missing data invalidated the conclusions presented in the JAMA article: ***six of the seven serious gastrointestinal complications that occurred in the second half of the study were in patients taking Celebrex.***

103. Pharmacia had presented a statistical argument to the FDA justifying its omission of the data from the second half of its study. The company claimed that since a higher percentage of people taking diclofenac dropped out of the study because of minor symptoms like heartburn, the data from the second half of the study were invalid because of what is called "informed censoring." Pharmacia argued that these dropouts would have gone on to develop serious gastrointestinal complications, and their dropping out of the study artificially minimized the risk of serious complications in the people taking diclofenac. The FDA flatly rejected this argument. It countered that there was no proof that the people with heartburn would have developed more serious

gastrointestinal problems. Further, the FDA GI reviewer concluded that if minor symptoms caused people in the study to stop taking diclofenac, people in the real world would similarly stop taking the drug if it caused heartburn and would similarly protect themselves from going on to develop serious gastrointestinal complications.

104. The FDA's opinion of the manufacturer's decision to publish only half of the data from its study was clear: "[T]he sponsor's presentations of 6-month data ... are not statistically valid or supportable." The FDA's gastroenterology reviewer concluded that the first six months of data – which had been presented in the JAMA article as if they were a report of the entire study – were not worthy of separate consideration: "Based on the lack of adequate rationale, these post-hoc analyses will not be further discussed or presented in this review." Looking at the data from the entire year of the study, the FDA's gastroenterology reviewer concluded that "***the sponsor has failed to demonstrate a statistically significant lower rate" of serious GI complications in the people who took Celebrex compared with the people who took the other NSAIDs.*** When the reviewer looked at only the second six months of data (*i.e.*, the data that had not been published in the JAMA article), he ***concluded that the risk of serious GI complications appeared to be higher in the people who took Celebrex "compared to both ibuprofen and diclofenac***" (emphasis in original). This was hardly an endorsement for a drug whose only advantage (besides the convenience of a once-daily dosing) was that it supposedly caused fewer serious GI problems.

105. The disparity between the CLASS article published in JAMA and the information in the FDA's files by no means stopped there. The primary question that the CLASS study had been designed to answer had been changed, producing results that were far more favorable to the manufacturer. The original research design submitted to the FDA by the manufacturer of Celebrex had stated: "The primary objective of this study is to compare the incidence of ***clinically significant*** [major] upper gastrointestinal events … in patients taking Celebrex to patients taking NSAIDs." The term "***clinically significant***" refers to complications that would generally require hospitalization: active bleeding, perforation of the stomach or duodenum requiring surgery, or obstruction of the outlet of the stomach. The research plan specifically called for the less serious

gastrointestinal side effects to "be categorized and analyzed separately." Indeed the FDA's gastroenterology reviewer specifically commented that the plan to identify the "truly significant" serious gastrointestinal complications alone was a "major strength of the current study."

106. But when the results of the study were published in JAMA, the incidences of major and minor gastrointestinal complications were combined. Why the change? The results of the study as originally designed failed to show that the people who took Celebrex developed significantly fewer major gastrointestinal complications than the people who took ibuprofen or diclofenac, even for just the first six months. ***Only by combining the minor GI symptoms with the more serious gastrointestinal complications could the artide conclude that Celebrex caused a statistically significant decrease in gastrointestinal complications compared with the other NSAIDs.*** As noted above, when the FDA looked at the results of the CLASS study in terms of the research question that had ***originally*** been posed, Celebrex was not significantly safer than the other NSAIDs.

107. Finally, the most important measure of safety is the overall frequency of serious side effects – including, but not limited to, gastrointestinal side effects. For the full 12 months of the study, ***the people in the CLASS study who took Celebrex experienced 11 percent more serious complications*** (in all body systems combined) than the people who took the older and less expensive anti-inflammatory drugs. This difference did not reach statistical significance but certainly is significant in countering Pharmacia's claim that Celebrex is better than older NSAIDs because it's safer.

108. These findings contributed to the FDA's decision to send one of its rare "Warning Letters" to the CEO of Pharmacia in February 2001. The letter cites repeated unsubstantiated marketing claims that Celebrex is the preferred NSAID for people taking a blood thinner and that it is safe and effective for the treatment of acute pain – a use for which it was not approved – and points out that Pharmacia's marketing material fails to warn of the possibility of serious GI complications caused by the drug. The Warning Letter concludes by saying:

> Your promotional activities described above raise significant health and safety concerns in that they minimize crucial risk information

> and promote Celebrex for unapproved new uses. In two previous untitled letters dated October 6, 1999, and April 6, 2000, we objected to your dissemination of promotional materials for Celebrex that … contained unsubstantiated comparative claims, and lacked fair balance. Based upon your written assurances that this violative promotion of Celebrex had been stopped, we considered these matters closed. Despite our prior written notification, and notwithstanding your assurances, Pharmacia has continued to engage in false or misleading promotion of Celebrex.

109. Also included in the Warning Letter was the requirement that Pharmacia send out the "Dear Healthcare Provider" letter. Of course, the letter sent out by the manufacturer was not quite as specific as the FDA's Warning Letter. Few doctors, even if they had bothered to wade through the difficult language, had the time or inclination to find out the story behind the letter. As a result, ***doctors continue to this day to prescribe Celebrex for their patients based on the "scientific evidence" published in JAMA***, not understanding that it was incomplete and presented an inaccurate picture of the so-called safety advantage of Celebrex over other less expensive NSAIDs.

E. Use of the CLASS Study to Promote Sales of Celebrex

110. The JAMA article falsely concluded that Celebrex was associated with a lower incidence of complications than NSAIDs.

111. The flawed conclusions of CLASS were widely distributed and believed by physicians. Tens of thousands of reprints of CLASS were bought from the publisher and a recent search of the Science Citation Index yielded 169 articles citing it, more than 10 times as many citations as any other article published in the same issue. The reprints were used by the Celebrex sales team to convince doctors that the "scientific evidence" showed that Celebrex was safer for their patients than older, less expensive NSAIDs. The wide distribution of the JAMA article purporting to present the results of the CLASS study increased sales of Celebrex.

112. According to the BRITISH MEDICAL JOURNAL, Volume 324, June 1, 2002, many physicians still believe the CLASS study:

> Publishing and distributing overoptimistic short term data using post hoc changes to the protocol, while omitting disappointing long term data of two trials, which involved large numbers of volunteers, is misleading. While some of the problems related to CLASS were

> partially covered in the news sections of BMJ and other journals, it was not emphasised how flawed the trial actually was, and how inadequate the authors' justifications. Consequently, CLASS may still be relied on by many physicians without reference to these flaws. In our experience most still believe the findings published originally. For example, most of 58 physicians attending an osteoarthritis workshop in Berne, Switzerland, in December 2001 had not realized that CLASS was seriously biased.

113. The JAMA article was critical to the launch of Celebrex. Once a drug is introduced into the market and establishes itself at a certain price point, unless there is a withdrawal of the drug, that price point remains. By use of the incomplete study information published in JAMA, as well as other misleading statements, Defendants were able to establish the price of Celebrex.

F. Misleading Articles in Medical Journal Used to Establish Celebrex in the Marketplace

114. Defendants also used the placement of misleading articles in prestigious journals as a means to falsely promote Celebrex. Defendants placed articles, through paid consultants, in prestigious journals including JAMA, ARCHIVES OF INTERNAL MEDICINE and other publications.

115. An example is a "Special Article" appearing in ARTHRITIS & RHEUMATISM, Vol. 43, No. 9, September 2000, entitled *Recommendations for the Medical Management of Osteoarthritis of the Hip and Knees*. These guidelines, endorsed by the American College of Rheumatology (the professional society of arthritis specialists, became the gold standard for treatment of osteoarthritis ("OA"). Three out of four of the expert authors had financial relationships with Searle and Pharmacia. These guidelines state if non-pharmacologic therapies (like heat, ice, and physical therapy) fail to provide adequate relief from osteoarthritis pain, drug treatment should be initiated with acetaminophen (Tylenol). If acetaminophen provides inadequate relief, the next drugs recommended were COX-2 specific inhibitors, not conventional NSAIDs. Without regard for the proscription included in the FDA's new drug approval letter to Searle about Celebrex, the guidelines assert that COX-2 inhibitors, based on endoscopic studies, have an advantageous safety profile. The FDA's letter of December 31, 1998 addressing this issue stated:

> " … any promotional use of endoscopic data without the qualifying explanations of that data found in the approved labeling … will be considered false and misleading." [Label: The correlation between findings of endoscopic studies, and the relative incidence of

clinically serious upper GI events that may be observed with different products, has not been fully established.]

Nonetheless, the authors of these guidelines concluded that COX –2 inhibitors, based on endoscopic studies, have an advantageous safety profile. Referring to the CLASS study, the authors noted that data from this study had not yet been published.

116. Medical journals that publish articles can add substantially to their income selling reprints to drug companies. Drug companies in turn give these reprints to their sales force who provide these to doctors as proof of a drug's superiority or qualities.

117. The publication of these guidelines [OR DO YOU WANT IT TO SAY: the "Special Article" helped] establish the use of COX-2 inhibitors as the standard drug therapy for the treatment of OA. Defendants purchased reprints of this article and it was used to promote the use of Celebrex for OA patients. As a result of such use, Celebrex became the standard course of treatment in such patients.

118. At the time these guidelines were written, the results of the CLASS study had not yet been published (the two articles were published almost simultaneously in September of 2000), but Defendants were aware of the results of the CLASS study. When the results of the CLASS study were published in JAMA, showing that Celebrex does not significantly reduce the risk of serious GI complications in comparison to other NSAIDs, Defendants did not seek to correct the guidelines, and continued to distribute reprints despite the fact that the guidelines did not reflect the best available scientific evidence. The authors, being paid by the pharmaceutical industry, did not print a correction and these guidelines continued to be used by physicians as the prescribing standard.

119. The guidelines *may* have been formulated on the best evidence that had been published at the time they were issued in the September 2000 issue of ARTHRITIS & RHEUMATISM. But the CLASS study had been completed by March 2000 – and certainly this information *should have been included* in the guidelines that were issued in September 2000 and remained in effect through the time that Vioxx was taken off the market. These guidelines were available continuously on the government sponsored guidelines website, www.guideline.gov, during that

time. There was no revision of the posted guidelines when the results of the CLASS study were (such as they were) published in JAMA the same month, September 2000. The CLASS study showed that among the subset of patients taking aspirin, those treated with Celebrex experienced no fewer GI complications than those treated with older, less expensive NSAIDs – even for the first six months of the study that were published. Nor were the guidelines updated when the FDA "Warning Letter" dispelled the claim that Celebrex is safer than other NSAIDs in patients on anti-coagulants. Nor were they updated with the data from the February 2001 Advisory Committee Meeting became available to the public on the FDA's website.

120. The guidelines listed factors that increase the risk of GI bleeding, and said that COX-2 inhibitors (Celebrex and Vioxx at the time) were the drugs of choice (after acetaminophen) for people at elevated risk. Even though the FDA reviewers dispelled that argument at the February 2001 Advisory Committee Meeting, the guidelines remained in place, not reflecting the updated information that should have caused them to be revised. Furthermore, in a section of the guidelines labeled "Initiation of treatment in the patient who is not at increased risk for an upper GI adverse event," the guidelines state:

> The approach recommended for treatment of patients not at increased risk for an upper GI adverse event is similar to that described above (Table 3) [for people at increased risk]

In other words, for patients at increased risk and for those not at increased risk of GI complications, the guidelines recommend treatment with a COX-2 selective inhibitor if acetaminophen does not provide adequate relief – even though the FDA GI reviewer concluded that Celebrex offers a safety advantage for neither group. These guidelines set the standards of good medicine and are admissible in malpractice cases as evidence of community standards.

121. Another example of the use of flawed studies to promote Celebrex use arises from publication of the article *The Coxibs, Selective Inhibitors of Clyclooxygenase-2* that appeared in the NEW ENGLAND JOURNAL OF MEDICINE, Vol. 345, No. 6, on August 9, 2001. Though prohibited by the then editorial policy of the New England Journal of Medicine, both of the authors received money from Searle and/or Pharmacia. The authors concluded that, "clinical trials have

demonstrated that treatment with highly selective cyclooxygenase-2 inhibitors [Celebrex and Vioxx] causes significantly fewer serious gastrointestinal adverse events than does treatment with non-selective NSAIDs." However, with the results of CLASS publicly available on the FDA website for seven months at the time this review article was published, the authors and Defendants were (or should have been) aware that there was no evidence of Celebrex being less likely to cause serious GI complications than other NSAIDs. Despite the error in this report, reprints of it were used by Defendants' sales force to market Celebrex to doctors.

122. Another example of the use of flawed studies to promote Celebrex use is contained in a corporate-sponsored review article appearing in the BRITISH MEDICAL JOURNAL on September 21, 2002, where one of the authors was employed by Pfizer, which promoted falsely the safety of Celebrex over NSAIDs:

> In this review of randomised controlled trials we have shown that celecoxib is as effective as other NSAIDs for the relief from symptoms of osteoarthritis and rheumatoid arthritis. The confidence intervals around the point estimates of efficacy were reasonably narrow, which mean that it is unlikely that there were clinically important differences. Compared with other NSAIDs, however, celecoxib showed increased upper gastrointestinal safety and tolerability. Rates of withdrawal due to gastrointestinal adverse event, dyspepsia, and abdominal pain were 40-60% lower, while the incidence of ulcers and serious upper gastrointestinal events was 40-75% lower.

123. This review was published 2-1/2 years after the CLASS study was completed, and Pfizer was aware that CLASS did not support this conclusion, yet Pfizer took no corrective steps with respect to publication of this article.

G. Defendants Provide Doctors With Misleading Literature

124. Prior to the publication of CLASS, Defendants continuously sent doctors materials that were false and misleading in order to create and expand the Celebrex markets. For example, in 1999, Defendants Searle and Pfizer co-promoted a series of slides used by the sales force, claiming that NSAIDs resulted in $500 million in excess medical care costs for GI diseases. The implication intended was that Celebrex did not cause GI diseases. There was no scientific basis for such a

claim and CLASS demonstrated otherwise, yet these claims stayed alive in the minds of physicians and helped promote Celebrex sales. This claim was never retracted or corrected by Defendants.

125. In 1999, Defendants sent literature to the medical community claiming that Celebrex demonstrated "significantly fewer GI ulcers in 12-week serial endoscopy studies." After CLASS was published, Defendants never corrected the misleading impressions created by this type of statement.

126. At panel presentations to doctors on Celebrex, Defendants presented statistics showing costs arising from NSAID-associated GI diseases, juxtaposed against claims regarding "new Celebrex" and its effectiveness. This juxtaposition was designed to falsely convey the GI safety and cost/effectiveness of Celebrex. Also included were slides stating Celebrex "safely" delivers relief, again intending to create the false impression the older, less expensive NSAIDs were not as safe.

127. After CLASS was completed, none of these misleading safety claims were corrected by Defendants.

128. After CLASS rejected GI claims, Defendants did not correct the misleading impression they had created. Further, these claims were made in written materials ***after*** the FDA rejected the use of endoscopic studies as a basis for claiming safety:

> FROM CELEBREX NEW DRUG APPROVAL LETTER 12/31/98:
>
> Please note that any advertising and/or promotional activity of this product will be considered false and/or misleading under Section 502 of the Act if it presents suggestions or representations that COX-2 selectivity confers on the product any claims of safety beyond what has been demonstrated in clinical studies and presented in the approved labeling. Additionally, promotional activities that make or imply comparative claims about the frequency of clinically serious GI events compared to groups of NSAIDs or specific NSAIDs will be considered false and/or misleading without differences having been demonstrated in adequate, well-controlled studies. Finally, any promotional use of the endoscopic data without the qualifying explanations of that data found in the approved labeling (paragraph beginning on line 251 in the enclosed label text) will be considered false and/or misleading. If you have any questions or concerns about this matter please contact the Center for Drug Evaluation and Research's Division of Drug Marketing, Advertising and Communications.

129. In a January 2000 letter to thousands of "Healthcare Professionals," jointly authored by Searle and Pfizer, Defendants described Celebrex as the "#1 selling brand of prescription arthritis medicine" and noted that "serious GI toxicity can occur with … NSAIDs." The message, no such GI toxicity occurs with Celebrex, this claim was unsupported and its falsity was never corrected.

130. In 2000, Pfizer and Searle sent doctors a description of Celebrex indicating that it has "excellent GI tolerability." Again, this was part of a successful effort to create the impression that Celebrex caused significantly fewer GI problems than the older, less expensive NSAID. This statement was misleading when made and never corrected.

131. In 2000, Defendants jointly agreed to send doctors materials describing Celebrex as a "scientific breakthough" which was not the case. Celebrex has no "breakthrough" clinical advantage over the older, less expensive NSAIDs.

132. In 2000, Defendants jointly agreed to send doctors materials claiming that Celebrex was more effective in pain relief than naproxen. This claim was based on a study published in 1999 [Pharmacotherapy 19(11):1269-78, 1999], in which the primary endpoint was functional status and Celebrex and naproxen were equivalent. The finding that Celebrex reduced pain more than naproxen was post-hoc, and therefore of far less importance. The FDA Medical Officer Review commented on the results of CLASS:

> While these protocols were not primarily intended to address effectiveness, it is disappointing that celecoxib at four times and twice the upper recommended dose for OA and RA, respectively, appeared to offer no substantial therapeutic gains.

133. All of the above materials are examples of false and misleading materials that conveyed superiority claims that persist in the medical community and led to the astounding success of Celebrex.

H. Marketing and Promotion

134. With the knowledge that Celebrex provides no better pain relief than older anti-inflammatory drugs (in fact, all doses of Celebrex provide significantly less relief in studies of dental pain than two over the counter Advil tablets) and that Celebrex is no less likely to cause

serious GI complications, Defendants continued pouring money into advertising campaigns that uniformly emphasized the gastrointestinal safety of Celebrex and its relief of symptoms.

135. Pharmacia and Searle spent more than $78 million on consumer advertising for Celebrex in the year 2000. Defendants spent more than $400 million on direct-to-consumer advertising for Celebrex from 1999 to 2003. Defendants' direct-to-consumer advertising had as its goal convincing patients that Celebrex was clinically superior to older, less expensive NSAIDs and that they should see their doctors and request a prescription for Celebrex. This was accomplished by use of the messages set forth below.

136. In addition, Defendants' sales forces have blitzed doctors' offices with literature and verbal presentations designed to convince both doctors and consumers that Celebrex was a superior drug for treatment of osteoarthritis, acute pain in adults, painful menstrual cycles and other types of disease. They aggressively promoted Celebrex as an improvement over other NSAIDs, like naproxen and ibuprofen, because it had a lower risk of side effects such as gastrointestinal ulcers and bleeding. Defendants did not promote or provide balanced presentation of Celebrex.

137. Such marketing efforts to physicians have become commonplace in recent years. Drugs, including Celebrex, that might once have been used primarily by specialists are routinely promoted to, and prescribed by, doctors who are less familiar with the drugs' full research record. Drug companies, with Pfizer in the forefront, spent billions on such "detailing" to physicians – *i.e.*, sales people dropping by to leave marketing materials and drug samples, and speaking to physicians about their companies' drugs.

138. Such large-scale marketing efforts have paid huge dividends to Defendants and other drug companies. The number of blockbuster drugs, defined as drugs with more that $1 billion in annual retail prescription sales, was only 15 in 1999 but grew to 34 in 2003.

139. As a result of Defendants' uniformly misleading advertising campaigns, Celebrex was wildly successful. Celebrex became Pharmacia's best selling drug with more than $2.6 billion in sales for 2000 and $3.1 billion in sales for 2001. After acquiring Pharmacia, Pfizer has

continued to enjoy blockbuster sales of Celebrex, with $2.7 billion in revenue from U.S. sales (out of $3.3 billion in worldwide sales) in 2004.

I. Examples of Misleading Materials Designed to Promote Celebrex as Offering a Heretofore Unavailable Improvement in the Quality of Life and/or as Providing Superior Pain Relief

140. Despite the lack of scientific evidence to support such claims, Defendants' advertisements often focused on one of two themes that were either expressly stated or implied by the words and images. One was that Celebrex provided previously unavailable improvements in quality of life. The second was that Celebrex provided superior pain relief.

141. The marketing plans for Celebrex were premised on an FDA approval that did not require a GI warning so that Defendants could claim that Celebrex was superior to NSAIDs and Vioxx. The marketing plan went forward in large measure with a concerted effort to disguise the true scientific evidence about the safety and efficacy of Celebrex.

142. From 1999 through the present, Defendants have repeatedly engaged in misleading advertising devised to portray Celebrex as safer than other pain relievers.

143. For example, on October 16, 1999, the FDA sent Defendant Searle a letter regarding misleading claims with respect to Celebrex. The FDA found as follows:

> NDA #20-998
>
> - Searle claims that, "With more than 5 million patients on Celebrex, physicians know what to expect when they prescribe Celebrex — the new standard of care for analgesic and anti-inflammatory therapy in the management of pain for OA and RA." This statement makes a broad superiority claim comparing Celebrex to not only the class of NSAIDs, of which Celebrex is a member, but to all analgesic and anti-inflammatory therapies available for the management of osteoarthritis (OA) and rheumatoid arthritis (RA). However, this global superiority claim has not been demonstrated by substantial evidence. Therefore, this claim is false or misleading.
>
> - Searle also presents several unsubstantiated comparative claims to Vioxx (rofecoxib), including but not limited to, "Why should I use Celebrex over Vioxx? My first response to your question leads me to ask, 'With all the experience that you and thousands of other physicians just like you have with the proven efficacy and benefit of superior safety of Celebrex, why wouldn't you want to prescribe Celebrex?'" (emphasis

> added). This claim suggests Celebrex has a "superior safety" profile compared to Vioxx, when such has not been demonstrated by substantial evidence. Therefore, DDMAC considers this unsubstantiated comparative claim to be false or misleading.

144. Typical of Defendants' misleading advertising is an advertisement called "Guitar TV ad." The Guitar TV advertisement in its entirety makes a representation about the indication and benefits of Celebrex for osteoarthritis or rheumatoid arthritis. A woman playing an acoustic guitar is featured. The visuals focus on her hands/fingers and playing ability (*i.e.*, she finger-picks the strings with one hand while executing chord changes with the other hand). These images are accompanied by a voice-over: "With Celebrex, I will play the long version." Together, these images and claims suggest that because of using Celebrex, there is a direct benefit to this patient's wrist/hand/finger joints related to movement and flexibility such that she can now play the long version of the song whereas she previously could not.

145. This advertisement is just one of many designed to have consumers believe that Celebrex will provide better relief or in some way improve the quality of their lives more than older, less expensive NSAIDs, many of which are available without a prescription.

146. Recently, the FDA issued a warning letter regarding this advertisement:

> While the Guitar TV ad suggests a direct benefit to this patient's wrist/hand/finger joints related to movement and flexibility, it fails to state the actual approved indication (*e.g.*, relief of signs and symptoms of osteoarthritis). It also fails to include any risk information about Celebrex, thus omitting the major side effects and contraindications (including warnings and precautions) of Celebrex as required by 21 CFR 202.1(e)(1). Omission of this information implies that there are no risks to the patient who takes Celebrex, which overstates the drug's safety.

147. Similarly the FDA found another Celebrex TV advertisement to be misleading. The FDA described this advertisement as follows:

> *Announcer: "Celebrex presents, arthritis tips."*
>
> Woman dressed as doctor: "Arthritis is the most wide-spread crippling disability in the United States today. Arthritis is the predominant cause of activity limitations and is a major determinate of nursing home institutionalization for the elderly. One out of every 7 people and 1 in every 3 families is affected by arthritis. If you feel any pain or discomfort in your joints, contact your local doc."

Announcer: "These arthritis tips have been brought to you by Celebrex."

148. The FDA found this advertisement to be misleading.

The Arthritis Tips TV ad is a product-specific drug ad for Celebrex that is misleading because it omits important information about the drug's safety and effectiveness and makes unsubstantiated effectiveness claims. The ad promotes Celebrex by identifying the drug by name at the beginning and end of the ad. Moreover, stating that Celebrex is presenting/bringing you arthritis tips clearly suggests that Celebrex is an arthritis treatment. The Arthritis Tips TV ad purports to quantify the disease burden of "arthritis" ("the most widespread crippling disability in the United States today … the most predominant cause of activity limitations and … a major determinate of nursing home institutionalization for the elderly. One out of every 7 people and 1 in every 3 families is affected by arthritis.") Finally, the Arthritis Tips TV ad directs viewers to contact their local doctor "if you feel any pain or discomfort in your joints" and follows this statement with another reference to Celebrex.

Overstatement of Effectiveness. The Arthritis Tips TV ad is misleading because it overstates the proven effectiveness of Celebrex for the treatment of "arthritis." The Arthritis Tips TV ad discusses the serious progressive effects of arthritis, noting that it commonly can lead to "crippling disability" and "nursing home institutionalization of the elderly." The viewer is then instructed "if you feel any pain or discomfort in your joints, contact your local doc. These arthritis tips have been brought to you by Celebrex." The totality of this presentation therefore suggests that Celebrex is an effective treatment for preventing or modifying the progression of arthritis, such that crippling disability and nursing home institutionalization may be avoided.

Celebrex is indicated only for relief of the signs and symptoms of OA and RA. Celebrex is not indicated for disease modification (i.e., altering the course of the progression of arthritis). Moreover, we are not aware of substantial evidence or substantial clinical experience demonstrating that treatment with Celebrex will prevent crippling effects or disability due to arthritis or prevent nursing home institutionalization of elderly patients with arthritis. Therefore, your Arthritis Tips TV ad greatly overstates the proven benefits of Celebrex.

Omission of Risk Information. The Arthritis Tips TV ad fails to disclose any risk information about Celebrex and thus omits the major side effects and contraindications (including warnings and precautions) of Celebrex as required by 21 C.F.R. 202.1(e)(1). Omission of this information implies that there are no risks to the patient who takes Celebrex, thus overstating its safety.

149. In the same letter the FDA found that various Celebrex print advertisements made unsubstantiated claims with respect to less expensive alternative drugs:

Unsubstantiated Superiority Claims

The print ad features the prominent headline "Strength They Can Stay With" and shows a chart comparing Celebrex, Ibuprofen and Naproxen, titled "6-Month Patient Persistency Rate." Over the chart is the statement, "In a study of approximately 1 million patients, persistency rates of different OA/RA treatments were assessed at 6 months." The tagline below the Celebrex logo in the print ad is "Proven strength that lasts."

The above referenced claims imply that Celebrex is more effective (i.e., stronger) than ibuprofen and naproxen for treatment of osteoarthritis or rheumatoid arthritis and that patients "stay with" or are more compliant with Celebrex therapy than the compared products. We are not aware of substantial evidence or substantial clinical experience to support these claims. The cited retrospective retail pharmacy database analyses by NDC Health, "Persistency Analysis: Celebrex, Vioxx, and All Other NSAIDs," August 2002 and "Persistency Analysis: Celebrex, Vioxx, Ibuprofen, and Naproxen," from November 2002 (almost 2 years ago), do not contain any data or information demonstrating that patients found Celebrex to be more effective than the other products, or that patients will be more "persistent" or compliant with Celebrex therapy. Moreover, the database information did not note the indication for which the drug was prescribed, so the suggestion that these rates reflect specifically OA/RA patients is misleading. In addition, the analyses do not account for factors that affect persistence or compliance such as cost insurance coverage, side effects, dosage regimen, and ease of use. Therefore, the analyses do not constitute substantial evidence or substantial clinical experience demonstrating that OA/RA patients are more compliant with Celebrex or stay on Celebrex longer because it is more effective than other products for the treatment of OA or RA.

150. Since its introduction, Defendants have issued promotional material designed to tie Celebrex to improving quality of life. It has distributed materials making numerous dramatic claims tied to the drug regarding quality of life, in terms of being able to do personal and work-related activities. A Pfizer infomercial shows people returning to their work and activities. These patients go from not being able to work or do anything they want to do, to being able to work and do everything they want to do, pain-free. Patients talk about being able to "do anything," "do as much as I want to do," being "back to doing what I do," and such. They talk about "enjoying life" again, how the drug improved their "quality of life," and how the drug "gave them back their lives" (a theme repeated over and over in the advertisement and in the background music). One person

states that "you can be free." Another states that the medicine "brought new vitality in life." Everyone portrayed has 100% efficacy in all of these outcomes.

151. Such claims are misleading and purport to promote Celebrex as superior. In fact, as the FDA has recently noted, "none of the comparative studies with naproxen, ibuprofen, and diclofenac to-date has been designed to demonstrate superiority or a specified degree of similarity in a rigorous way."

152. In addition, Defendants caused to be published the following advertisements which were designed to appeal to consumers or doctors which misstated or deceptively conveyed Celebrex's superiority.

153. TELEVISION ADVERTISEMENT: ***The "I Will Not" advertisement***. This campaign, ran in October 2003 and April 2004, portrays people engaging in various physical activities. The tag line for the advertisement is "With Celebrex I will not …" This is followed by various variations in this theme.

a. The advertisement shows a woman jogging with announcer stating: "With Celebrex I will no longer give in to the joint pain of osteoarthritis. Just one Celebrex provides up to 24 hour relief from the pain of osteoarthritis."

b. The advertisement shows a woman playing golf with announcer stating: "With Celebrex I will not stop at 9 when I really want to play 18." The announcer further states: With Celebrex I will not settle for part time relief. If you are struggling with joint pain maybe you should stop trying to manage it by yourself."

c. The advertisement shows a woman running on a beach, a woman playing golf, people doing tai chi, a man pitching softball, a couple hiking, a man pushing a child on a marry-go-round, a man swimming and a woman kayaking. The advertisement has a small disclaimer that runs for a few seconds on the bottom of the screen that says, "Individual results may vary."

154. Each of the "I Will Not" foregoing advertisement scenes overstate the effectiveness of Celebrex. Each implies complete pain relief and complete return of movement and functionality

for all patients which is not representative of the results from Celebrex clinical trials. And each misrepresents the fact that the relief provided by Celebrex is not superior to that provided by older, less expensive NSAIDs, several of which are available without a doctor's prescription. The small disclaimer regarding individual results hardly counteracts the overall message of this advertisement.

155. The "I Will Not" advertisement makes unsubstantiated superiority claims. By stating that "if you are struggling with joint pain maybe you should stop trying to manage it by yourself" the advertisement falsely implies that Celebrex is superior to over-the-counter NSAIDs, and created unnecessary physician visits by conveying the message a doctor can prescribe a medication that is superior to those available without a prescription.

156. TELEVISION ADVERTISEMENT: ***The "Fixing the Preschool" advertisement.*** The theme of this campaign, ran during May 2001, is a group of people fixing up a building that will be a preschool. The advertisement starts out with the announcer: "If you have osteoarthritis there is reason to celebrate … Celebrex." The advertisement then shows people engaging in various activities repairing the schoolhouse. It shows a man on a ladder taking down a sign with the text: "Mark, arthritic shoulder." It shows a woman cleaning a blackboard with the text: "Sarah, arthritic back." The announce states, "Celebrex specifically targets only the Cox-2 enzyme – a key source of arthritis pain. Celebrex relieves arthritis pain plus stiffness too." The advertisement shows a woman working with a trowel with the text: "Julia, arthritic hands." The announcer states: "Powerful 24 hour relief from osteoarthritis pain, inflammation and stiffness." The advertisement has a small disclaimer that runs for a few seconds on the bottom of the screen that says "Individual results may vary."

157. This campaign overstates the effectiveness of Celebrex and implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. The small disclaimer regarding individual results does not counteract the overall message of this advertisement.

158. This advertisement campaign makes unsubstantiated superiority claims. By stating that "Celebrex specifically targets only the Cox-2 enzyme – a key source of arthritis pain" it falsely implies that it is superior to other NSAIDs.

159. TELEVISION ADVERTISEMENT: ***"The Softball Game" Advertisement.*** The theme of this advertisement, run during September 2000 and May 2001, is a softball game. The advertisement starts out with the announcer stating: "If you have osteoarthritis there is reason to celebrate … Celebrex." The announcer states: "Celebrex specifically targets only the Cox-2 enzyme – a key source of arthritis pain. 24 hour relief from pain and stiffness." The ad shows a woman helping a young boy to bat with the text: "Jill, arthritic hands." It shows a group of women doing the wave with the text: "Rita, arthritic back." It shows the umpire raising his arms with the text: "John arthritic shoulder." The advertisement has a small disclaimer that runs for a few seconds on the bottom of the screen that says "Individual results may vary."

160. This advertisement overstates the effectiveness of Celebrex. It implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. The small disclaimer regarding individual results does not counteract the overall message of this advertisement.

161. This advertisement makes unsubstantiated superiority claims. By stating that "Celebrex specifically targets only the Cox-2 enzyme – a key source of arthritis pain" it falsely implies that it is superior to other NSAIDs.

162. TELEVISION ADVERTISEMENT: ***"A Day in the Park" Advertisement.*** The theme of this advertisement, ran during November 2000, is people engaging in various activities in a park. The advertisement starts with a theme song "celebrate, celebrate do what you like to do." The announcer states: "If you have osteoarthritis there is reason to celebrate it's Celebrex. Powerful 24 hour relief from osteoarthritis pain and stiffness. Celebrex is the first arthritis medicine that targets only the Cox-2 enzyme." The advertisement shows people doing tai chi with the text: "Ann, arthritic shoulder." The ad shows a man and a child riding push scooters with the text: "Bill, arthritic knee." It shows a man rowing a boat with the text: "Dave, arthritic shoulder."

It shows a woman pushing a child on a swing with the text: "Liz, arthritic back." The advertisement has a small disclaimer that runs for a few seconds on the bottom of the screen that says "Individual results may vary."

163. This advertisement overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. The small disclaimer regarding individual results does not counteract the overall message of this advertisement.

164. This advertisement makes unsubstantiated superiority claims. By stating: "Powerful 24 hour relief from osteoarthritis pain and stiffness. Celebrex is the first arthritis medicine that targets only the Cox-2 enzyme" the ad falsely implies that Celebrex is superior to other NSAIDs.

165. TELEVISION ADVERTISEMENT: ***"I Will Not ..." Advertisement #2.*** The advertisement portrays people engaging in various physical activities. The tag line for the ad is: "With Celebrex I will not give in to the pain of osteoarthritis." The advertisement shows a man swimming, a couple canoeing and a woman running. The announcer states: "Just one Celebrex provides up to 24 hour relief from the pain of osteoarthritis." The ad shows a woman playing golf with a voice over: "With Celebrex I can line up my putt." It shows woman playing a guitar with the voice over: "I can play the long version." The announcer states: "One pill, 24 hours so you can live your life the way you want. With Celebrex I will not settle for part time relief." The advertisement shows people hiking, a woman painting a chair, a man fishing, a woman playing a guitar, people doing yoga and a man pushing a merry-go-round. The announcer states, "If you are suffering from pain, inflammation or stiffness maybe you should stop trying to manage it on your own." The advertisement has a small disclaimer that runs for a few seconds on the bottom of the screen that says "Individual results may vary."

166. This advertisement overstates the effectiveness of Celebrex. It implies complete pain relief and complete return of movement and functionality for all patients which is not

representative of the results from Celebrex clinical trials. The small disclaimer regarding individual results hardly counteracts the overall message of this advertisement.

167. The advertisement makes unsubstantiated superiority claims. By stating that "if you are suffering from pain, inflammation or stiffness maybe you should stop trying to manage it on your own" the advertisement implies that it is superior to over-the-counter NSAIDs which is not supported in clinical trials. By stating, "with Celebrex I will not settle for part time relief" the advertisement implies that it is superior to other arthritis treatments which is not supported in clinical trials.

168. TELEVISION ADVERTISEMENT: ***"Dancing" Advertisement***. The theme of this advertisement, ran during July 2002, is people dancing. The advertisement shows a couple dancing with a voice over that states: "Even with osteoarthritis these arms still have a way with the ladies." The text on screen says: "Arthritic Elbow." The next scene shows a woman dancing with a voice over that states: "These legs hardly miss a beat" with text "arthritic knee." The next scene shows a couple dancing with the voice over: "These hands haven't lost their touch" with text "arthritic hands." The announcer states: "Just one Celebrex last 24 hours. Provides powerful arthritis pain relief that is non-narcotic." The advertisement has additional footage of the above people dancing. The advertisement has a small disclaimer that runs for a few seconds on the bottom of the screen that says "Individual results may vary."

169. This advertisement overstates the effectiveness of Celebrex. It implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. The small disclaimer regarding individual results does not counteract the overall message of this advertisement.

170. Each of the foregoing advertisements also failed to disclose the increased risk of heart problems that were known to Defendants at the time Celebrex was launched. Defendants concealed a study completed June 24, 1999 comparing Celebrex to placebo for the slowing of the progression of Alzheimer's Disease and overall safety. Patients taking Celebrex were 3.6 times more likely to experience a serious cardiovascular event (2.1% of patients taking placebo vs. 7.7%

of patients taking Celebrex).[6] Pfizer's report of this study shows that the increased risk of cardiovascular complications in patients taking Celebrex was statistically significant.[7] Furthermore, among patients taking Celebrex there were 12% more serious adverse events (25.6% vs. 22.9%) and 59% more deaths (4.6% vs. 2.9%). The study was never published and was not presented to the FDA in time to be included in the February 2001 Advisory Committee Meeting that considered the safety of Celebrex. Had the findings from this study been published and disclosed to the FDA in a timely manner, sales of Celebrex — based primarily on the claimed safety advantage over older, less expensive NSAIDs — would have been dramatically less. These findings would have been of singular importance to prescribing doctors given the concern, appropriately express in the JAMA article reporting the first six months of the CLASS study, about the theoretical risk of increased adverse events disturbing the clotting balance with selective COX-2 inhibition:

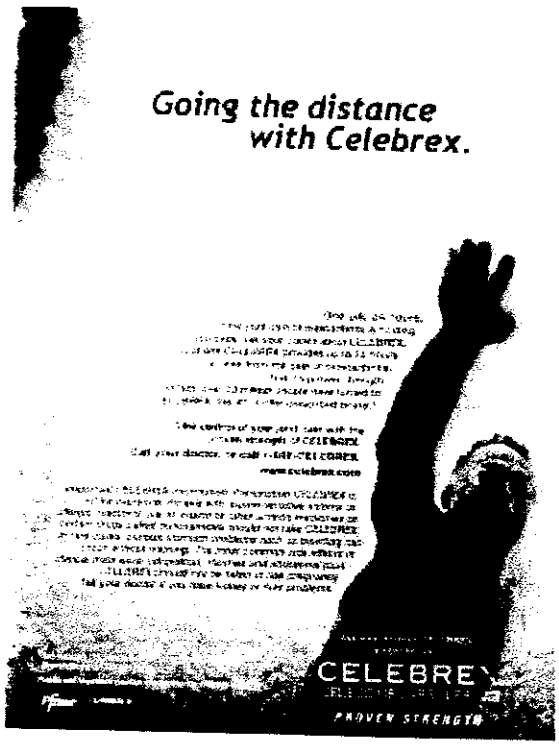
> Although it has been hypothesized that COX-2–specific inhibitors might increase the risk of cardiovascular thromboembolic events via inhibition of vascular prostacyclin synthesis without a corresponding inhibition of platelet thromboxane, no such increase was evident in the current study.

Pharmacia's failure to make the results of this study available are particularly vexing, because it was completed eight months before the CLASS study was completed, and it's results should have informed the report published in JAMA.

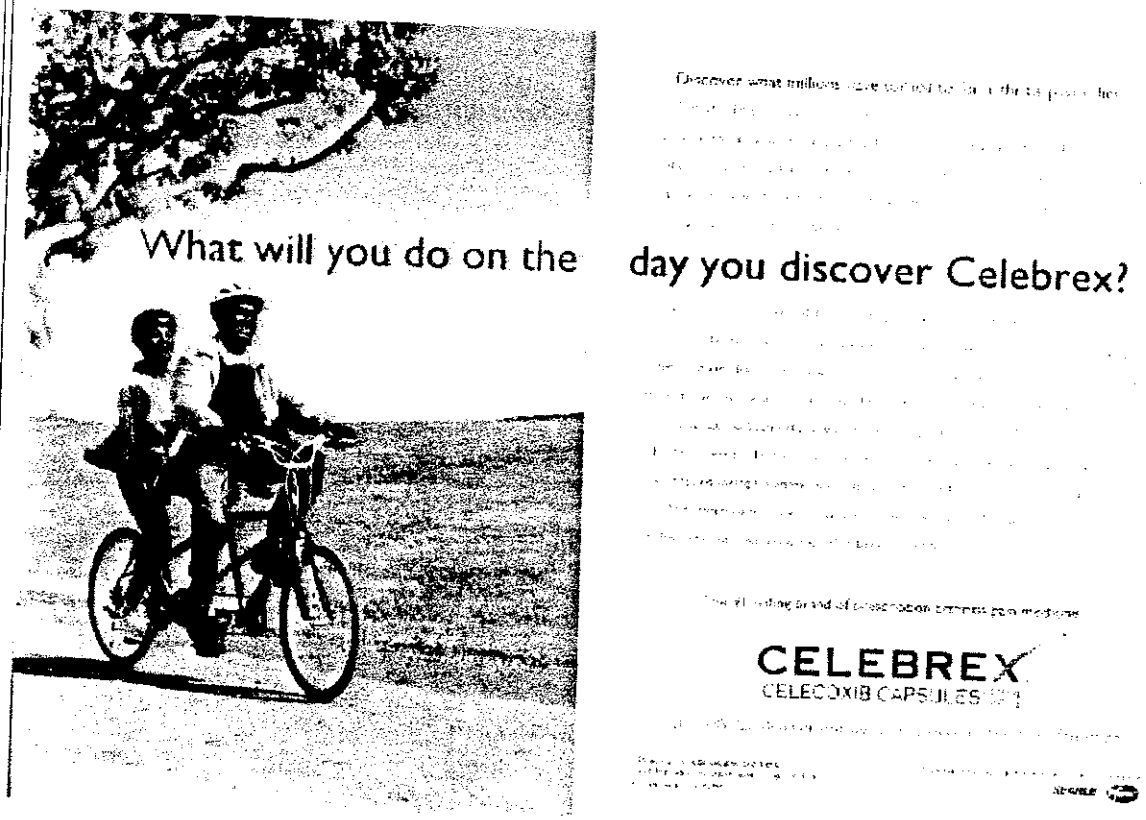
171. As part of the scheme alleged herein, Defendants engaged in a massive direct-to-consumer advertising campaign in the print media designed to create consumer demand for Celebrex. The following is a sampling of such advertisements.

[6] Letter to FDA revealing heart dangers in an unpublished clinical trial of Celebrex (HRG Publication #1721), Public Citizen, January 31, 2005. http://citizen.org/publications/release.cfm?ID=7359

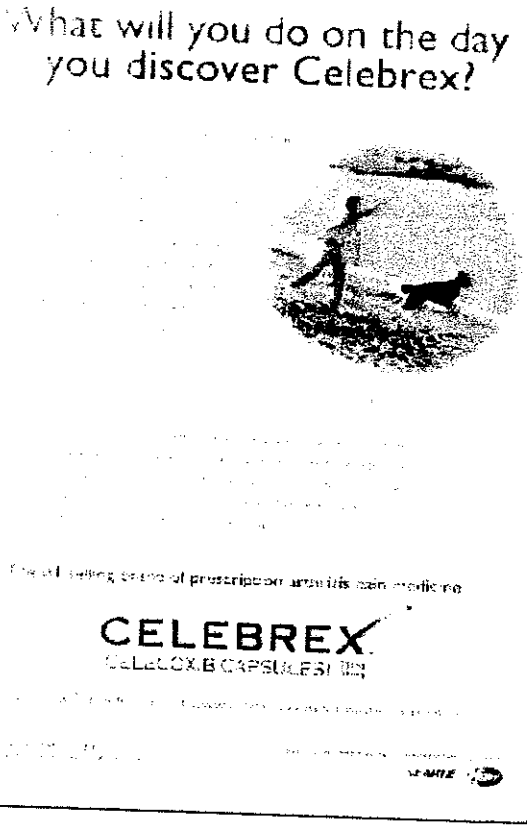
[7] A statistically significant difference favoring placebo in adverse events was observed for certain CV-related body system terms (Cardiovascular Disorders, General; Heart Rate and Rhythm Disorders; Myo, Endo, Pericardial & Valve Disorders). These differences were primarily driven by the individual terms cardiac failure, fibrillation atrial, and angina pectoris. http://www.clinicalstudyresults.org/documents/company-study_76_0.pdf



172. This advertisement which ran during October 2003, in its entirety, overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. It also seeks to bolster its image and acceptance by claiming that 23 million people are using it and by virtue of the fact it is the "#1 doctor-prescribed drug." However, these figures, if true, are misleading by virtue of acceptance of Celebrex was the result in large measure to Defendants' deceptive scheme for marketing Celebrex.



173. This advertisement which ran during January 2000 overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. This advertisement makes unsubstantiated superiority claims. The advertisement claims that Celebrex is a "breakthrough" implying that it is superior to other NSAIDs which is not supported in clinical trials, and in fact is misleading given the lack of statistical significance between Celebrex and older NSAIDs, and the lack of disclosure of the cardiovascular risks presented by Celebrex. It also represents that it is the "#1 selling brand" which would not have been the case if Defendants had not engaged in the unlawful scheme described herein.



174. This advertisement which ran during March 2000 overstates the effectiveness of Celebrex. The advertisement implies complete pain relief and complete return of movement and functionality for all patients which is not representative of the results from Celebrex clinical trials. This advertisement makes unsubstantiated superiority claims without disclosure of cardiovascular risks. The advertisement claims that Celebrex is a "breakthrough" implying that it is superior to other NSAIDs which is not supported in clinical trials.